Oncotech	Declaration of Conformity

EC Declaration of Conformity

Name of medical product: **The Ophtascan™ software**

Manufacturer	ONCOTECH NORDIC AB
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Single Registration Number (SRN):	SE-MF-000026046

This declaration of conformity is issued under the sole responsibility of the ONCOTECH NORDIC AB

Object of the declaration	
Medical Product:	**The Ophtascan™ software**
EMDN Code:	V92
Classification:	Class I
MDR rule:	Rule 11 of Annex VIII
Basic UDI-DI	7300009081085569890O1CZ

We, **ONCOTECH NORDIC AB**, ensure and declare under our sole responsibility that the listed product **Ophtascan™ software** to which this Declaration of Conformity relates is in conformity and meet the provisions of Regulation (EU) 2017/745, which apply to them and covered by CE mark.

Ophtascan™ software have been classified as Class I, according to Annex VIII, Rule 11 and is in conformity with the General Safety and Performance requirements and provisions of the Regulation (EU) 2017/745 concerning medical devices.

Conformity assessment is in accordance with Regulation (EU) 2017/745, article 52 (section 7). Applied standards: EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 14971:2019+A11:2021, ISO/TR 24971:2020, IEC 62366-1:2015/AMD1:2020, IEC 62304:2006/A1:2015, IEC 82304-1:2016.

Signed for and on behalf of **ONCOTECH NORDIC AB**

Andre Rafnsson

(signature)

Place and Date: Vejbystrand, Sweden, 30-06-2022